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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	No. 2:15-MD-02641-DGC **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION AND INCORPORATED MEMORANDUM TO EXCLUDE THE OPINIONS OF DAVID KESSLER, M.D. AND MEMORANDUM OF LAW IN SUPPORT** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

MOTION

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move to exclude the opinions of Plaintiffs' regulatory expert witness,

Dr. David Kessler, because Plaintiffs cannot meet their burden of establishing that Dr. Kessler's opinions, including his opinions that Bard did not comply with United States Food and Drug Administration ("FDA") regulatory requirements, satisfy the admissibility standards of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Federal Rules of Evidence 702 and 401-403.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Dr. Kessler is not a fact witness, IVC filter expert, or plaintiff's lawyer. He does not wear a black robe. Yet plaintiffs have paid him over $750,000 to fill all of these roles. (*See* July 31, 2017, Deposition of Dr. David Kessler ("Kessler Dep. II"), attached as Exhibit F, at 32:24 to 34:6; Updated Invoice, attached as Exhibit G.) He is the quintessential "superlawyer" purporting to serve as a "scientifically informed advocate[] of conclusions that plaintiff wants the jury to reach and which belong only in summation, not expert testimony." *Hogan v. Novartis Pharms. Corp.*, No. 06 Civ. 0260(BMC)(RER), 2011 WL 1533467 at *5 (E.D.N.Y. Apr. 24, 2011) (excluding in full the testimony of another regulatory expert who attempted to play the role of fact witness, scientific expert, attorney, and the Court).

Dr. Kessler, a former FDA commissioner, has a law degree. He has taught food and drug law and testified before Congress about legal issues. Left unchecked he will trade on this experience to supplant the Court and personally instruct the jury about what law to apply. He will then argue Plaintiffs' case as if he was standing at counsel's podium, not seated on the witness stand. While he gives lip service to the proscription against witnesses offering legal opinions, he has no intention to abide by any such restraints as the plain language of his report makes clear: "In my opinion … Bard violated the Federal Food Drug and Cosmetic Act." (*See* Supplemental Report, attached as Exhibit B, at ¶ 97.) Indeed, his reports are replete with string cites to case law and read more like summary judgment briefs than the analysis one would expect from a dispassionate expert.

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Dr. Kessler spins a slanted narrative of Bard's alleged malfeasance all with the false imprimatur of the FDA itself. His reports collectively total over 340 pages, not counting an additional 448 pages of "Schedules" that Plaintiffs' counsel prepared for him. (*See* Report, attached as Exhibit A; Supp. Report, attached as Exhibit B; Second Supp. Report, attached as Exhibit C; Schedules, attached as Exhibit D.) The sheer length of his various expert reports obfuscates the true bases of his opinions and, by design, prevents any meaningful determination of what he will actually say at trial. As a result, Dr. Kessler's opinions cover the full scope of plaintiffs' theories of liability regardless of whether they are tied to FDA regulations and irrespective of the scientific or medical discipline required for expert testimony on a given subject. His prejudicial narrative is particularly problematic because what Bard or the FDA did or did not do is a purely factual inquiry for the jury, and Dr. Kessler's criticisms of the FDA itself, and speculation as to what the FDA would have done with certain information, have no place in the courtroom. Moreover, his policy critique of the law, including the 510(k) process, is better served in the halls of Capitol Hill than to a jury who will unfairly judge Bard for complying with regulations Congress debated and passed. As set forth more fully below, the Court should exclude Dr. Kessler's improper opinions.

II. ARGUMENT AND CITATION OF AUTHORITY

A. The Court Should Exclude Dr. Kessler's Improper Legal Conclusions and Attempts To Instruct the Jury on the Law.

It is universally accepted that expert witnesses cannot give legal opinions. *See Pinal Creek Grp. v. Newmont Mining Corp.*, 352 F. Supp. 2d 1037, 1042 (D. Ariz. 2005) ("The principle that legal opinion evidence concerning the law is inadmissible is so well-established that it is often deemed a basic premise or assumption of evidence law—a kind of axiomatic principle.") (internal quotation omitted). This holds true for "legal expert testimony which defines the governing law" as well as "legal expert opinion which applies the law to the facts." *Id.* Expert legal opinions are flatly prohibited because "the judge is the sole arbiter of the law and its application to the facts . . . ." *Id.* As such, "the

Ninth Circuit has . . . excluded legal expert testimony concerning both what the law is and how it should be applied to the facts of the case." *Id.* (citing *Aguilar v. International Longshoremen's Union Local # 10*, 966 F.2d 443 (9th Cir.1992)); *see also*, *Oakberg v. Zimmer, Inc.*, No. CV–03–47–BU–SHE, 2004 WL 5503779, at *2 (D. Mont. Nov. 23, 2004) ("[The plaintiffs' regulatory expert] may not offer opinions relating to the content of FDA regulations, the application of FDA regulations to Defendant's operations, Defendant's alleged violations of FDA regulations, or FDA regulatory clearance or reporting requirements."), *aff'd in pertinent part, rev'd in part on other grounds*, 211 F. Appx. 578, 580 (9th Cir. 2006) (affirming the court "had a proper basis to conclude that the proposed testimony did not rest on a reliable foundation and that the experts were not qualified").

In addition to being a former FDA commissioner and a medical doctor, Dr. Kessler has a law degree from the University of Chicago School of Law, as he states in the first paragraph of his expert report. (Ex. A, Rep. ¶ 1.) He quickly points out that he has taught food and drug law at Columbia University Law School and has testified before Congress on related legal issues. (*Id*. at ¶ 4.) With his legal background and substantial experience as an expert witness for plaintiffs against drug and device companies, it is not surprising that Dr. Kessler fully understands that he is not allowed to give legal opinions. (Ex. F, Kessler Dep. II, 93:2-9 ("I'm not going to give a legal opinion. . . . [U]ltimate legal questions I'll leave to the jury.").) What *is* surprising, however, is how blatant Dr. Kessler's actual legal opinions are. Indeed, as the exemplar opinions below demonstrate, the plain language of Dr. Kessler's expert reports flies in the face of the universally accepted prohibition against expert legal opinions and his own sworn admission that he will not provide them:

- "In my opinion, Bard promoted IVC filters for non-cleared uses in violation of the Federal Food Drug and Cosmetic Act. (Ex. B, Supp. Rep. ¶ 96.)

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- "In my opinion, Bard's promotion of IVC filters for non-cleared uses is evidence that Bard violated the Federal Food Drug and Cosmetic Act. (*Id.* at ¶ 97.)
- "In my opinion, the Recovery Filter fell below the quality to which it was represented and was thus, adulterated under the Federal Food Drug & Cosmetic Act. (Ex. A, Rep. at ¶ 15. *Id.* ¶ 19(c); *id.* ¶ 583.)
- "The Recovery filter could not serve as a predicate for the Modified Recovery (G2) filter if as, in my opinion, it became a violative product that was adulterated under the Federal Food, Drug & Cosmetic Act. Thus, the Modified Recovery (G2) filter could not enter the market under the 510(k) process. (*Id.* ¶ 19(e).)
- "[T]he G2 filter fell below the quality to which it was represented and was thus adulterated under the Federal Food, Drug & Cosmetic Act." *Id.* 19(f).
- "As a consequence of adulteration, the Bard Recovery filter could not be legally marketed." (*Id.* ¶ 563.)
- "[T]he G2 Filter, that had the Recovery Filter as its predicate, could not have been legally marketed." (*Id.* ¶ 570.)
- "Bard's Recovery Filters were not, nor could be claimed to be, substantially equivalent to their predicate device." (*Id.* ¶ 553.)

Even a cursory glance at Dr. Kessler's extraordinarily lengthy report reveals his intention to instruct the jury on the law, apply the law to the facts, and espouse legal conclusions. In many respects his report is indistinguishable from a summary judgment motion in substance and tone, replete with citation to case law and amicus briefs. On pages 21 through 24 of his MDL Report, he purports to interpret *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), including support for his arguments with discussion of the concurring opinion of "Justice O'Connor, with whom Chief Justice Scalia and Justice Thomas joined," and citations to legal journal articles. And, on pages 8 through 15 of his MDL Supplement, he supports his arguments with citations to amicus briefing and case

law from other circuits and federal district courts that are not binding on this Court, and the most recent of which is dated 2001. (*See, e.g.,* Ex. B, Supp. Rep. at ¶ 24 ("FDA and the courts have recognized that intended use may be shown by non-speech evidence" with footnote citation to a string-cite of four published cases); *id*. at ¶ 22 ("According to an appellate court reviewing this question: 'most, if not all advertising, is labeling . . . .'") (case law citation omitted).)

Notably, the amicus brief and case law on which Dr. Kessler relies have been affected by the voluminous body of case law and subsequent amicus briefs from the FDA issued over the past 16 years. In other words, Dr. Kessler is not simply helping the jury understand FDA regulations or providing regulatory or factual background. Rather, he is taking a legal position and supporting his arguments with carefully selected court opinions and briefs. He then uses his factual narrative, with documents and testimony that have been selected and summarized by Plaintiffs' counsel in the Schedules, to issue an opinion on Bard's ultimate liability.

Similarly, Dr. Kessler's testimony tracks his report in terms of Bard violating regulations, or selling "adulterated" or "misbranded" IVC filters, but the legal conclusions are nonetheless clear:

> Q Do you intend to offer any opinions as to whether the design of one or more of Bard's retrievable filters were defective?
>
> A Not as an ultimate legal matter as in terms of design defect. But certainly as the medical monitor said, you know, he thought it should be redesigned. Certainly when it failed it was adulterated. So in essence it should never have -- you know, it shouldn't have been -- seen the market or been left on the market because of its -- because it failed those tests. That's what I will testify to. So but it goes to adulteration and the industry standard not a question of ultimately whether there was a -- the legal question of the design defect.

(Ex. F, Kessler Dep. II, 129:25 to 130:13; *see also, id.* at 142:1-11 (testifying that the Recovery Filter was "adulterated" and that Bard made "misleading statements" about the Recovery Filter); *id.* at 92:24 to 93:9 ("That's a legal opinion. I'm not going to give a legal opinion. I do talk about the device not meeting certain standards, and that being – falling below either an industry standard or adulteration…or what a reasonably prudent

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manufacturer would do."); Dep. Tr. of Dr. David Kessler, 162:12-25, Oct. 5, 2016, ("Kessler Dep. I"), attached as Exhibit E ("There's nothing in the IFU for G2 that point out that it failed on caudal migration, there's nothing in there that shows there's increased risk of migration compared to SNF. So it's certainly misleading because it makes – the IFU makes it sound like this is all filters, when clearly there's evidence of increased risk.").) Through his expert witness experience, Dr. Kessler has learned to make some of his legal conclusions regarding regulatory compliance more subtle than others. But, this is a distinction without a difference; the import is the same. These are classic impermissible legal opinions and should be excluded. *See Miller v. Stryker Instruments*, No. CV 09-813-PHX-SRB, 2012 WL 1718825, at *10 (D. Ariz. Mar. 29, 2012) ("Regarding whether Defendant deviated from legal requirements of the FDA, it is the responsibility of the Court to instruct the jury about those legal requirements."); *Specht v. Jensen*, 853 F.2d 805, 810 (10th Cir.1988) ("[W]hen the purpose of testimony is to direct the jury's understanding of the legal standards upon which their verdict must be based, the testimony cannot be allowed."); *Heishman v. Ayers*, 621 F.3d 1030, 1042 (9th Cir. 2010) ("[I]t is within a district court's discretion to exclude proposed expert testimony concerning a legal standard of care . . . .") (citations omitted)).

B. The Court Should Exclude Dr. Kessler's Impermissible Factual Narrative.

Dr. Kessler's reports and corresponding "Schedules" amount to nearly 800 pages of his "personal" interpretation of documents and witness testimony, all with the false imprimatur of the FDA itself.[1] His cumbersome narrative is an impermissible end run

[1] Bard has highlighted the extensive portions of Dr. Kessler's Report, starting at page 32, and Supplemental Report illustrating his narrative testimony. Notably, much of Dr. Kessler's report is based on the Schedules that were prepared for him by Plaintiffs' counsel. In other words, Plaintiffs' counsel prepared schedules for Dr. Kessler setting forth their theory of the case, and Dr. Kessler prepared a report and based his opinions on that theory. (*See e.g.*, Ex. E, Kessler Dep. I at 80:4-14 (admitting that "[a]ll schedules were prepared by staff from legal counsel"); *id.* at 81:23 to 82:6 (admitting that he did not revise Schedule 2 at all); *id.* at 86:6-23 (admitting that individuals from multiple law firms helped prepare the Schedule related to migration testing and that he did not recall reviewing any specific migration testing while at FDA); *id.* at 92:2 to 105:17 (generally admitting that various Schedules were prepared for him by Plaintiffs' attorneys or their

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around the orderly admission of evidence at trial, which should come from witnesses with percipient knowledge, not from hired advocates. Experts are not necessary to present facts. As such, courts nationwide reject such attempts at using experts to circumvent the presentation of evidence directly to the jury. *See e.g., In re FEMA Trailer Formaldehyde Products Liab. Litig.*, Case No. MDL 07-1873, 2009 WL 2169224 (E.D. La. July 15, 2009) (excluding expert testimony merely opining as to the facts of the case because the expert's role was more akin to "the role of an 'über-juror' rather than as an expert [with opinions based on specialized knowledge]"); *In re Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323, 1339; 1346 (S.D. Fla. 2010) ("[The plaintiffs' regulatory expert's] 250 page Report...is broad and unwieldy: while each major opinion is followed by statements that are intended to provide the bases for that opinion, there is generally a striking disconnect between these statements and the major opinions . . . . [the regulatory expert] does not analyze the facts; she . . . regurgitates them and reaches conclusory opinions that are purportedly based on these facts. These facts should be presented to the jury directly . . . ."); *Miller v. Stryker Instruments*, No. CV 09-813-PHX-SRB, 2012 WL 1718825, at *10 (D. Ariz. Mar. 29, 2012) ("Regarding Opinions 1 and 2, whether Defendant marketed its pain pumps for certain indications is a matter of fact to be determined by the jury, and the Court finds that 'scientific, technical, or other specialized knowledge' is not necessary to help the jury make this determination. Indeed, much of [the plaintiffs' regulatory expert's] report regurgitates facts that should be submitted directly to the jury.").

Moreover, Dr. Kessler's sprawling narrative serves as an attempt to opine on all topics related to Bard's IVC filters because he argues that virtually every aspect of a medical device falls within FDA's purview. Because this testimony improperly invades the province of the jury and is unreliable, it should be excluded. Dr. Kessler's unwieldy report also obfuscates the bases for his opinions and makes it nearly impossible to learn what he will actually say at trial. Faced with a similar report, this Court has rejected such

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staff, that he did not decide what specifically was included in the Schedules, and that he did not revise or audit what they included).)

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data-dump tactics. *See Lopez v. I-Flow Inc.*, No. CV 08–1063–PHX–SRB, 2011 WL 1897548, *10 (D. Ariz. Jan. 26, 2011) **("**[The plaintiffs' regulatory expert's] report is a labyrinth that the Court cannot navigate . . . [the expert] spends 37 pages citing FDA regulations and guidelines but offers no analysis whatsoever to support her opinions. . . . In other sections, [the expert's] report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation.").

C. Dr. Kessler's Opinions about Information Allegedly Withheld from FDA and His Rank Speculation about What FDA Would Have Done with Allegedly Withheld Information Should Be Excluded Because They Are Irrelevant and Preempted.

"[E]xpert testimony that is merely speculation or pure conjecture based on the expert's impressions of the physical evidence must be excluded as not based on any reliable methodology or scientific principle." *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007) (also excluding the plaintiffs' regulatory expert's testimony to the extent it "is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA"). Dr. Kessler provides no basis for his speculative conclusions that Bard's filters would not have been cleared if certain information was disclosed to FDA:

> In my opinion, when new and continuing questions about safety and effectiveness are raised, the new device cannot be substantially equivalent to predicate devices….Bard's Recovery Filters were not, nor could be claimed to be, substantially equivalent to their predicate device…Bard's failure to disclose to the FDA the problem that it identified with its "short leg-span" Recovery Filter in 28mm diameter tube deprived FDA of important risk information that was relevant to Bard's 510(k) application. This disclosure would have been important to doctors and patients in deciding whether to use the Bard Recovery device.

(Ex. A, Rep. ¶¶ 100-102; *see also*, *id.* at ¶ 190 ("In my opinion, if Bard had removed the Recovery Filter from the market in April/May 2004, as I believe it should have, there would have been no legally marketed predicate for Bard to have claimed substantial equivalence for a new device. Thus the G2 Filter, that had the Recovery Filter as its

predicate, could not have been legally marketed."); Ex. C, Second Supp. Rep. at 11 n. 14 ("The Denali trial was not complete at the time Bard received clearance for its Denali filter and thus did not serve as a basis for the agency's clearance of the device."); Ex. E, Kessler Dep. I, 190:12 to 191:16 ("But the failure to meet the performance spec in the representation that Bard made to FDA was not disclosed to FDA. So G2 was worse than RNF, it was worse than SNF, it failed on the performance spec. That was never -- the basis of substantial equivalence was basically undercut by that test. That was never disclosed to FDA.").)

This speculation only serves as the implicit conclusion that Bard's IVC filters would not have, or should not have, been on the market (i.e., were defective). Dr. Kessler should not be permitted to speculate as to this ultimate legal issue or to second-guess the FDA. *See In re Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323, 1350 (S.D. Fla. 2010) (excluding the plaintiff's regulatory expert's opinion that Bayer "failed to fully disclose to FDA" certain information because "[the expert] was not a percipient witness to these events and is engaging in pure speculation as to the alternative outcome of a certain FDA meeting without providing any regulatory expertise or analysis.").

Furthermore, not only are these opinions completely speculative, but they should be excluded for an additional and independent reason: they are preempted.[2] *See*, *e.g.*, *Bouchard v. American Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) ("[e]vidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA"); *Block v. Woo Young Med. Co. Ltd.*, 937 F. Supp. 2d 1028, 1046 (D. Minn. 2013) ("The Court concludes that [the plaintiff's regulatory expert] cannot testify regarding an FDA standard of care or standard of conduct, to the extent that such a term indicates compliance with applicable

[2] Plaintiffs also may not "bootstrap" alleged failures to investigate and report adverse events to the FDA into a failure to warn or fraud case. *Webster v Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003); *see also Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423-24 (6th Cir. 2005) (plaintiff could not allege that "[D]efendant was negligent per-se in failing to comply with the FDA's conditions of approval" because that "is a disguised fraud on the FDA claim").

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FDA regulations. Implied preemption bars state tort claims that exist solely by virtue of FDCA requirements and include the existence of federal enactments as a critical element. . . . Stating that Woo Young violated an FDA standard of care, or offering similar testimony, will not be permitted. Similarly, [the plaintiff's regulatory expert] cannot testify that Woo Young is liable because it promoted its devices in manners inconsistent with the FDCA.") (quoting *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 352-53 (2001)). As a result, all of Dr. Kessler's opinions regarding regulatory compliance, other legal conclusions such as whether certain actions by Bard were "misleading," and speculation as to FDA action should be excluded.

D. Dr. Kessler Is Not Qualified To Opine on IVC Filter Design, Testing, Causation.

Through the course of his factual narrative and voluminous Report, Dr. Kessler offers many opinions for which he is not qualified under Rule 702 because they are areas that fall outside his purported regulatory expertise. Aside from courses in medical school, Dr. Kessler has no training in engineering (Ex. E, Kessler Dep. I, 16:18-23), and has never designed an implantable medical device (*Id.* at 18:1-22). Dr. Kessler is no longer a board certified physician, although his background is in pediatrics. (Ex. F, Kessler Dep. II, 18:11-23.) He has never treated a patient with regard to an IVC filter, and has never implanted or removed one. (*Id.* at 55:24 to 56:6.)

Yet, Dr. Kessler readily opines on topics far outside his qualifications under the theory that the FDA receives information related to all aspects of medical devices:

- Design - "In my opinion, even if those discussions with physicians and the literature reviews suggested a maximum venous pressure of 35 mmHg, the actual maximum pressure difference achieved in Bard's animal studies should have led Bard not to reference the 35 mmHg number." (Ex. A, Rep. ¶ 125.)
- Testing – "As discussed *supra*, in my opinion, the additional migration resistance specification that the G1A must withstand a minimum of 50mmHg pressure was based on a flawed engineering specification." (Ex. A, Rep. ¶ 356.)
- Causation – "In my opinion, by promoting its filters for non-cleared uses, Bard's promotional efforts were misleading for these non-cleared indications because these promotional efforts also failed to warn about the increased risk of movement/migration of its filters compared to permanent only filters. Bard's

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> misleading promotion of non-cleared uses expanded the number of patients who received the device and put that population at increased risk for fracture and migration of the device." (Ex. B, Supp. Rep. ¶ 100.)

However, simply because data is submitted to the FDA, which has a multitude of divisions and employees with unique and separate expertise, does not automatically qualify Dr. Kessler to opine on these topics. *See e.g.*, *Reece v. Astrazeneca Pharm., LP*, 500 F. Supp. 2d 736, 744-45 (S.D. Ohio 2007) ("It is clear, however, from [the plaintiff's regulatory expert's] report, deposition testimony, and testimony at the oral hearing and plaintiff's summary judgment brief that [the plaintiff's regulatory expert] seeks to offer testimony and opinions on matters that go well beyond FDA procedures and regulations and her areas of expertise. . . . Specifically, [the expert] seeks to offer the opinions that defendants failed to provide physicians with adequate warnings and directions for the use of Crestor . . . [the expert] is not qualified to offer such opinions because although she is a medical doctor, plaintiff has not demonstrated that there is anything in [the expert's] background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure.").

E. Dr. Kessler's Opinions Regarding Corporate Intent and Ethics Are Not Reliable and Would Not Assist the Jury.

"Personal views on corporate ethics and morality are not expert opinions." *In re Baycol*, 532 F. Supp. 2d at 1053. Additionally, "[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony." *In re Rezulin,* 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004); *see also, In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding the plaintiffs' regulatory expert's "conjecture" regarding the "knowledge, motivations, intent, state of mind, or purposes" of pharmaceuticals manufacturer); *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla. 2015) (excluding similar opinions in a Bard IVC Filter case because "[the plaintiff] fails to demonstrate that these opinions are reliable or relevant to this case. The Engineers themselves do not purport to have any expertise on the relevant ethical or professional standards, and they do not identify the ethical or professional standard on

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which they base this opinion. As such, these opinions appear to be simply their subjective views on how a medical device manufacturing company should act, and therefore, are due to be excluded as unreliable.").

Dr. Kessler's "opinions" on Bard's state of mind and corporate ethics should be excluded because they are unreliable and do not assist the jury. Despite having no basis for these speculative, *ipse dixit* opinions, Dr. Kessler cannot contain his testimony: "Bard knew, you know, that there was migration at – or very early on in the G2 and knew what fixes had to take place . . . ." (Ex. F, Kessler Dep. II, 130:14 to 131:6; *see also*, *id*. at 147:1-15 ("[T]he company with regard to Eclipse failed to ensure the safety. Because you didn't put – you didn't strengthen the anchors with regard to Eclipse. You didn't do that until Meridian. Your client didn't do that until Meridian. It didn't fix the problem it had seen. It knew that that was an issue and didn't address it. In fact it only did it by electropolishing."); *id*. at 39:17 – 40:2 ("But not in the ethical -- well, I'll leave others to talk about ethics, whether -- I'm not going to talk about ethics, but I have, again, considerable concern…"); Ex. B, Supp. Rep. ¶ 5 ("[T]o address the problems with the Modified Recovery (G2), G2X and Eclipse filters, Bard decided it needed the addition of "caudal anchors to improve the resistance to caudal migration in comparison to the Eclipse/G2X/G2 filters,"); *id*. at ¶ 102 ("Bard targeted physicians to use Bard IVC filters for prophylactic non-cleared uses to expand the market for IVC filters.").) Although Dr. Kessler claims that these types of opinions are based on documents he reviewed, that is impermissible expert testimony which should be left to the jury. *In re Prempro Prod. Liab. Litig.*, 554 F. Supp. 2d 871, 883 (E.D. Ark. 2008) (excluding the plaintiffs' regulatory expert's opinion that defendant's conduct "would not be appropriate from a public health point of view in terms of women's safety" because this opinion was devoid of regulatory analysis) *aff'd in pertinent part, rev'd in part on other grounds*, 586 F.3d 547, 573 (8th Cir. 2009) ("The admission and the jury's consideration of [the plaintiffs' regulatory expert's] testimony, however, amounted to prejudicial error, and thus the appropriate remedy is a new trial.").

III. CONCLUSION

Dr. Kessler's opinions are not only inadmissible under Rule 702, but are also unhelpful and unreliable under *Daubert*. Accordingly, the Dr. Kessler's opinions should be excluded in their entirety.

DATED this 24th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that August 24, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Matthew B. Lerner
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